

**GOLDMAN ISMAIL TOMASELLI BRENNAN & BAUM LLP**

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May 10, 2013

**VIA FAX**

The Honorable Cathy Seibel  
United States District Judge  
The Hon. Charles L. Brieant Jr. Federal Building and U.S. Courthouse  
300 Quarropas St.  
White Plains, NY 10601-4150

**Re: *In re: Mirena IUD Products Liability Litigation*, 13-MD-2434 (CS)  
Proposed Agenda for Initial Conference and Proposed Schedule**

Dear Judge Seibel:

Pursuant to Order No. 1, Bayer HealthCare Pharmaceuticals Inc. ("Bayer") submits (1) an agreed proposed agenda for the Initial Conference and (2) Bayer's proposed schedule for pretrial activities in this MDL.

The parties have reached agreement on a proposed agenda, which is included as Attachment A to this letter. Bayer's proposed schedule is set forth below. Counsel for Plaintiffs has not provided Bayer with Plaintiffs' proposed schedule.

**Status of the Litigation**

Unlike many newly-formed MDLs, the Mirena litigation has advanced far beyond the initial phases of litigation. The parties have been litigating Mirena cases for years and have already completed significant discovery.

The case that had advanced the furthest before multi-district transfer was the *Baugh* case in the U.S. District Court for the District of South Carolina. The lead plaintiff's counsel in *Baugh* (Fred Thompson of Motley Rice) is one of the proposed Lead Counsel for Plaintiffs in this MDL. *Baugh* was stayed pending consolidation just one week before the close of discovery and three months before trial. During a discovery period that spanned six months, Bayer produced millions of pages of documents, and Plaintiff deposed multiple Bayer witnesses. The document production included the entirety of Bayer's correspondence with and submissions to the FDA concerning Mirena as well as relevant documents within the custodial files of five key Bayer employees. Bayer's dispositive motions are fully briefed.

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**Proposed Science Day Presentation to the Court**

To promote efficiency in this already well-developed litigation, Bayer believes it may benefit the Court to hold a hearing this summer during which counsel for Bayer and Plaintiffs can present on the scientific issues relevant to the litigation. The Court could invite state court judges in New Jersey and elsewhere to participate in this Science Day presentation by phone, videoconference, or in person.

**Limited Additional Generic Fact Discovery of Bayer**

Given the significant progress already made in the litigation, a protracted period of generic fact discovery is unwarranted. Plaintiffs are not entitled to unfettered discovery requests and limitless depositions of Bayer employees. As the JPML reasoned when forming this MDL, the 41 served cases in the MDL all involve factual issues common to the *Baugh* case. The consolidation of other cases asserting similar allegations to *Baugh* does not necessitate a voluminous expansion of Bayer's discovery burden.

Bayer stands ready to produce the millions of pages that were produced in the *Baugh* litigation, as well as the transcripts of the Bayer company witness depositions taken in that case. To facilitate that production, Bayer has provided a proposed Protective Order and Discovery Production Protocol to Plaintiffs' counsel. Bayer hopes to be able to reach prompt agreement on these drafts with counsel and submit them to the Court in short order.

While discovery is substantially complete, Bayer is willing to voluntarily produce certain supplemental materials without requiring formal discovery requests. First, Bayer will update the sources of documents in the *Baugh* production to include records existing as of the date of the initial status conference before this Court. Second, Bayer will produce relevant documents from the custodial files of up to five additional Bayer employees involved with Mirena. Third, Bayer will voluntarily produce documents and data from certain databases and shared drives at Bayer. Finally, Bayer will present up to five additional Bayer employees for deposition.

The parties should proceed expeditiously toward the disposition of an initial pool of cases. With proper limits in place, Bayer believes generic discovery can be complete by December 2013.

**Case-Specific Discovery**

Given that the FDA-approved label for Mirena warns of the claimed injuries, which are well-known among doctors, case-specific discovery of Plaintiffs' medical records and depositions of Plaintiffs and their prescribing physicians will be critical to the disposition of these cases. To speed progress toward this disposition, case-specific discovery should proceed concurrently with generic discovery of Bayer.

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Bayer proposes that either party should be permitted to notice a deposition in any case beginning 30 days after the Plaintiff completes a Plaintiff Fact Sheet and authorizes the release of medical records. During this initial phase of case-specific discovery, Bayer would agree to limit the number of depositions within a single case. This initial discovery will facilitate the selection of an Initial Disposition Pool of cases by December 2013.

**Initial Disposition Pool Selection and Workup**

In December 2013, after all generic discovery and significant case-specific discovery has been completed, Bayer expects that the parties and the Court will be in a position to select a limited number of cases for prompt initial disposition. After allowing two months to complete any remaining case-specific discovery in this pool of cases, the parties can then proceed to generic expert discovery and case-specific expert discovery in the Initial Disposition Pool cases, followed by *Daubert* and dispositive motions. Bayer anticipates that rulings on such motions will be instructive to the parties and will promote a timely and just resolution of the MDL as a whole.

With these considerations in mind, Bayer respectfully proposes the following schedule:

<b>Date</b>	<b>Deadline</b>
June 7, 2013	Parties file a proposed Protective Order, Discovery Production Protocol, Plaintiff Fact Sheet, and medical records authorizations with the Court
14 days after entry of Protective Order	Bayer begins rolling document production
30 days after Order adopting Plaintiff Fact Sheet	All Plaintiffs in MDL as of May 17, 2013 will complete Plaintiff Fact Sheets and related medical records authorizations. (All other Plaintiffs will complete Plaintiff Fact Sheets within 30 days of filing/transfer to the MDL.)
July 2013	Science Day Presentation to the Court (and other judges wishing to join)
30 days after service of completed Plaintiff Fact Sheet in any case	Any party may begin conducting initial case-specific discovery in that case
December 16, 2013	Generic Fact Discovery Deadline
December 16, 2013	Initial Disposition Pool Selection
February 14, 2014	Case-Specific Discovery Deadline in Initial

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	Disposition Pool
March 14, 2014	Deadline for Plaintiffs' Generic Expert Disclosures and Case-Specific Expert Disclosures in Initial Disposition Pool cases
April 14, 2014	Deadline for Bayer to Depose Plaintiffs' Generic Experts and Case-Specific Experts in Initial Disposition Pool cases
April 28, 2014	Deadline for Bayer Generic Expert Disclosures and Case-Specific Expert Disclosures in Initial Disposition Pool cases
May 28, 2014	Deadline for Plaintiffs to Depose Bayer Generic Experts and Case-Specific Experts in Initial Disposition Pool cases
June 30, 2014	<i>Daubert</i> and Disposition Motion Deadline in Initial Disposition Pool cases

Respectfully submitted,



Shayna S. Cook  
*Lead Counsel for Defendant*  
*Bayer HealthCare Pharmaceuticals Inc.*

CC (via email):

Counsel for Plaintiffs Diogenes P. Kekatos, Fred Thompson, James R. Ronca, Matthew McCauley; Counsel for Bayer Marie Woodbury, James Shepherd, and William Harrington

# Attachment A

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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IN RE:

MIRENA IUD PRODUCTS LIABILITY LITIGATION

13-MD-2434 (CS)

*This Document Relates To All Actions*  
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**PROPOSED AGENDA ITEMS**  
**FOR MAY 17, 2013 INITIAL CONFERENCE**

1. **Introductions.**
2. **Lead and Liaison Counsel Structure.** Plaintiffs' recommended structure has been forwarded to the Court pursuant to Section VII(D) of Order No. 1 filed in this case on 4/12/13.
3. **Overview of Mirena Products Litigation.** The parties have submitted to the Court their respective position papers regarding the litigation to date pursuant to Section IV of the above-referenced Order No. 1.
4. **Direct filing of additional actions.** By letter dated May 10, 2013, Counsel for Bayer advised the Court of its position on a direct-file provision.
5. **Pro hac vice motions/necessity of local counsel.**
6. **Identity of all federal actions and the current MDL transfer status.** List previously submitted in accordance with CMO 1. Update Court as to any filings since May 10, 2013.
7. **Identification of all pending motions and current status.**
8. **Status of state court litigation.** Status of motion for coordination in New Jersey State Court and matters pending in St. Louis, Missouri.
9. **Whether Pilot Project orders should apply to this MDL litigation.**
10. **Scheduling of status conferences.** The parties agree that regular monthly status conferences are necessary early in the MDL process.
11. **Proposed Schedule for Pre-Trial Activities.** The parties agree to meet and confer on the following topics in the 30 days following the designation of Lead and Liaison Counsel for plaintiffs and to prepare proposals for submission to the Court:

Master Complaint/Short-form Complaints/Master Answer;

Confidentiality Agreement/Protective Order;

Document production issues including electronically-stored information ("ESI") protocol;

Privilege log and redaction protocol;

Service of process;

Plaintiffs' and Defendant's fact sheet;

Authorizations and co-discovery of plaintiffs' records;

Preservation of evidence;

Production of medical records;

Proposed schedule for pre-trial discovery and trials;

Scope, timing, and limitations on expert discovery;

Amendment of pleadings;

*Baugh and Osborne* Cases;

1. Discussion of influence on the discovery schedule and overall discovery in these consolidated actions;
2. Early trial setting v. remand to transferor courts.

Early Dispositive Motions to narrow the issues; and

Separate Complaints v. Bundled Complaints.

**GOLDMAN ISMAIL TOMASELLI BRENNAN & BAUM LLP**

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**FACSIMILE TRANSMITTAL SHEET**

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**TO: THE HON. CATHY SEIBEL  
U.S. DISTRICT JUDGE**

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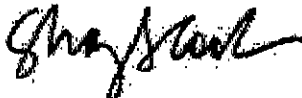
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**Re: *In re: Mirena IUD Products Liability Litigation*, 13-MD-2434 (CS)  
Proposed Agenda for Initial Conference and Proposed Schedule**

Dear Judge Seibel:

Pursuant to Order No. 1, enclosed please find a proposed agenda for the initial conference on May 17, 2013, and proposed schedule for pretrial activities in the above-named MDL.

Respectfully submitted,



Shayna S. Cook  
*Lead Counsel for Defendant*  
*Bayer HealthCare Pharmaceuticals Inc.*

Enclosures

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